UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

THE VLADIMIR GUSINSKY REVOCABLE TRUST, derivatively on behalf of MERCK & CO., INC. Plaintiff, v. ROBERT M. DAVIS, DOUGLAS M. BAKER, JR., MARY ELLEN COE, PAMELA J. CRAIG, THOMAS H. GLOCER, RISA J. LAVIZZO-MOUREY, STEPHEN L. MAYO, PAUL B. ROTHMAN, PATRICIA F. RUSSO, CHRISTINE E. SEIDMAN, INGE G. THULIN, KATHY J. WARDEN CAROLINE LITCHFIELD, and DEAN T. LI Defendants, and MERCK & CO., INC., Nominal Defendant.	:	Case No. VERIFIED SHAREHOLDER DERIVATIVE COMPLAINT JURY TRIAL DEMANDED

Plaintiff The Vladimir Gusinsky Revocable Trust ("Plaintiff"), by and through its attorneys, hereby submits this Shareholder Derivative Complaint (the "Complaint") for the benefit of Nominal Defendant Merck & Co., Inc. ("Merck" or the "Company"), against certain current and former officers and directors of the Company seeking to remedy breaches of fiduciary duties and unjust enrichment, from February 3, 2022 through the present (the "Relevant Period"). Plaintiff makes

these allegations upon personal knowledge and the investigation of counsel, which included, among other things, review and analysis of: a) public filings made by Merck and other related parties and non-parties with the Securities and Exchange Commission ("SEC"); b) press releases and other publications disseminated by certain of the Defendants and other non-parties; c) news articles, shareholder communications and postings on Merck's website; d) publicly available filings in a related securities class action lawsuit captioned *Cronin v. Merck & Co., Inc. et al.*, No. 2:25-cv-01208, in the U.S. District Court for the District of New Jersey (the "Securities Action"); and e) other publicly available information concerning Merck and the Individual Defendants (defined below under "Parties.") Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. Merck is among the world's largest pharmaceutical companies, touting itself as "at the forefront of research to deliver innovative health solutions that advance the prevention and treatment of diseases in people and animals." Specifically, the Company develops and manufactures prescription medicines, including biologic therapies, vaccines and animal health products.

2. Throughout the Relevant Period, Merck management touted its prescription drug Gardasil, representing, among other things, that the drug would

generate $11 billion in revenue by 2030. The Company boasted about its confidence in its ability to utilize successful consumer activation and education efforts regarding Gardasil's benefits to drive demand among eligible usage populations worldwide, primarily China.

3. Specifically, Merck issued false and misleading statements and/or concealed material adverse facts concerning Gardasil's true level of demand in China, including that Merck lacked any meaningful ability to assess demand for Gardasil in the region, resulting in the inflated inventory at its Chinese distributor, Zhifei.

4. On July 30, 2024, during Merck's earnings call held in conjunction with the Company's release of its second quarter fiscal year 2024 earnings, the Company announced a significant reduction in Gardasil vaccinations, and a resultant above normal inventory level of the drug at Zhifei. Although Merck purported to remain confident in its long-term projections both with regard to China and worldwide, it conceded that shipments of Gardasil to China could fall below contracted levels for 2024. On this news, Merck's stock price dropped almost 10%.

5. Still, Merck continued to mislead investors with regard to the demand for Gardasil. On October 31, 2024, the Company held an earnings call in conjunction with the release of its third quarter 2024 financial results, during which Company management repeated statements exhibiting confidence in Gardasil's

growth in China and Merck's ability to achieve $11 billion in worldwide Gardasil sales by 2030. Company management further touted Merck's efforts to assist Zhifei with promotional and educational resources to bolster Gardasil sales with reduced shipping levels, noting that such efforts had resulted in the reduction of overall channel inventory levels.

6. The full truth emerged on February 4, 2025, when Merck announced it would not achieve the oft-forecasted $11 billion in Gardasil sales by 2030, and that the Company would cease shipments of Gardasil to China "through at least midyear" to facilitate a necessary "rapid reduction of inventory."

7. On this news, Merck's common stock price immediately declined another near 10%, from $99.79 on February 3, 2025, to $90.74 per share on February 4, 2025.

8. Merck has suffered and will continue to suffer significant financial and reputational harm because of the wrongs committed by, among others, the Individual Defendants, including the Company's Board of Directors ("Board") and other members of management, as described below.

JURISDICTION AND VENUE

9. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(a)(2) in that Plaintiff and Defendants are citizens of different states and the matter in controversy exceeds $75,000.00, exclusive of interests and costs. This

Court has supplemental jurisdiction over the state law claims asserted herein pursuant to 28 U.S.C. §1367(a). This action is not a collusive one to confer jurisdiction on a court of the United States which it would not otherwise have.

10. This Court has jurisdiction over each Defendant because her or she resides in this district or has sufficient minimum contacts with this district to render the exercise of jurisdiction by the Court permissible under traditional notions of fair play and substantial justice. The Court has personal jurisdiction over the Nominal Defendant because it is authorized to do business in this state, has consented to service in this state and its principal place of business is within this district.

11. Venue is proper in this district pursuant to 28 U.S.C. § 1391 because one or more of the Defendants either resides, or maintains offices, in this district, a substantial portion of the transactions and wrongs complained of herein, including the Individual Defendants' (defined below) primary participation in the wrongful acts detailed herein and violations of fiduciary duties owed to the Company occurred in this district, and Individual Defendants have received substantial compensation in this district by doing business here and engaging in numerous activities that had an effect in this district.

PARTIES

12. Plaintiff is a current shareholder of Merck and has continuously held Merck common stock since June 3, 2004. Plaintiff is a resident of Illinois.

13. Nominal Defendant Merck is a New Jersey corporation with its principal executive offices in Rahway, New Jersey.

14. Defendant, Robert M. Davis ("Davis"), is Merck's president and chief executive officer ("CEO"). He also has been a board of directors ("Board") member since July 2021 and Board Chair since December 2022. Upon information and belief, Davis is a resident of New Jersey.

15. Defendant, Douglas M. Baker, Jr. ("Baker"), has served on the Board since 2021 and is a member of the Audit Committee and Research Committee. Upon information and belief, Baker is a resident of Minnesota.

16. Defendant, Mary Ellen Coe ("Coe"), has served on the Board since 2019 and is a member of the Board's Compensation and Management Development ("Compensation") Committee, Development Committee and Research Committee. Upon information and belief, Coe is a resident of California.

17. Defendant, Pamela M. Craig ("Craig"), has served on the Board since 2015, chairs the Board's Audit Committee and is a member of its Governance Committee. Upon information and belief, Craig is a resident of New York.

18. Defendant, Thomas H. Glocer ("Glocer"), has served on the Board since 2007, chairs the Board's Governance Committee and is a member of its Compensation Committee. Upon information and belief, Glocer is a resident of New York.

19. Defendant, Risa J. Lavizzo-Mourey ("Mourey"), has served on the Board since 2020, and is a member of the Board's Compensation Committee and Research Committee. Upon information and belief, Mourey is a resident of New Jersey.

20. Defendant, Stephen L. Mayo ("Mayo",) has served on the Board since 2021, and is a member of the Board's Audit Committee and Research Committee. Upon information and belief, Mayo is a resident of California.

21. Defendant, Paul B. Rothman ("Rothman"), has served on the Board since 2015, chairs the Board's Research Committee and is a member of its Audit Committee. Upon information and belief, Rothman is a resident of Maryland.

22. Defendant, Patricia F. Russo ("Russo"), has served on the Board since 1995, chairs the Board's Compensation Committee and is a member of its Governance Committee. Upon information and belief, Russo is a resident of Colorado.

23. Defendant, Christine E. Seidman ("Seidman"), has served on the Board since 2020, and is a member of the Board's Audit Committee and Research Committee. Upon information and belief, Seidman is a resident of Massachusetts.

24. Defendant, Inge G. Thulin ("Thulin"), has served on the Board since 2018, and is a member of the Board's Compensation Committee and Governance Committee. Upon information and belief, Thulin is a resident of Minnesota.

25. Defendant, Kathy J. Warden ("Warden"), has served on the Board since 2020, and is a member of the Board's Compensation Committee and Governance Committee. Upon information and belief, Warden is a resident of Virginia.

26. Defendant, Caroline Litchfield ("Litchfield"), was, at all relevant times, an Executive Vice President and the Chief Financial Officer ("CFO") of Merck. Upon information and belief, Litchfield is a resident of New Jersey.

27. Defendant Dean Y. Li ("Li") was, at all relevant times, an Executive Vice President of Merck and the President of Merck Research Laboratories. Upon information and belief, Li is a resident of New Jersey.

28. Defendants Davis, Baker, Coe, Craig, Glocer, Mayo, Mourey, Rothman, Russo, Seidman, Thulin, Warden, Litchfield and Li are referred to herein as the "Individual Defendants."

29. Defendants Baker, Craig, Mayo, Rothman, Seidman and Warden are referred to herein as the "Audit Defendants."

INDIVIDUAL DEFENDANTS' DUTIES

30. By reason of their positions as officers, directors, and/or fiduciaries of Merck, and because of their ability to control the business and corporate affairs of Merck, Individual Defendants owed the Company and its shareholders fiduciary obligations of good faith, loyalty, and candor, and were and are required to use their utmost ability to control and manage Merck in a fair, just, honest and equitable manner.

31. Further, Individual Defendants were, and are, required to act in furtherance of the best interests of Merck and its shareholders so as to benefit all shareholders equally, and not in furtherance of their personal interest and benefit. Each director and officer of the Company owes to Merck and its shareholders the fiduciary duty to exercise good faith and due diligence in the administration of the Company's affairs, and in the use and preservation of its property and assets, as well as the highest obligation of fair dealing.

32. Because of their positions of control and authority as directors and/or officers of Merck, having knowledge of material non-public information regarding the Company, the Individual Defendants were able to and did, directly and/or indirectly, exercise control over the wrongful acts complained of herein. To discharge their duties, the officers and directors of Merck were required to exercise reasonable and prudent supervision over the management, policies, practices and

controls of the Company. By virtue of such duties the officers and directors of Merck were required to, among other things:

1. Exercise good faith to ensure that the affairs of the Company were conducted in an efficient, business-like manner so as to make it possible to provide the highest quality performance of their business;
2. Exercise good faith to ensure that the Company was operated in a diligent, honest and prudent manner, and complied with all applicable federal and state laws, rules, regulations and requirements, and all contractual obligations, including acting only within the scope of its legal authority and disseminating truthful and accurate statements to the investing public; and
3. When put on notice of problems with the Company's business practices and operations, exercise good faith in taking appropriate action to correct the misconduct and prevent its recurrence.

33. Merck's Corporate Governance Guidelines state, in relevant part:

> ***The primary mission of the Board is to represent and protect the interests of the Company's shareholders. In so doing, the Board has the legal responsibility for overseeing the affairs of the Company and has certain specified powers and authorities with respect to corporate action provided by the New Jersey statutes.*** The Board's oversight function can and should be exercised through the election and appointment of competent officers. The Board nevertheless remains ***responsible for oversight and thus has an obligation to keep informed***

in order to assist management in formulating and developing plans; it also sets necessary criteria and serves as a body to ***review and advise management on the operations*** of the Company. These duties should be discharged by the full Board, the Board's committees, or the independent members of the Board, as appropriate in the circumstance.

Specifically, the Board, as a body or through its committees or members, should

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(c) Safeguard the corporate assets by periodically reviewing the financial affairs and policies of the Company and overseeing the Company's financial reporting process and internal controls,

(d) Oversee the Company's risk assessment process and ensure that the Company has appropriate procedures in place to manage risks and handle crises,

(e) Ensure the Company's compliance with applicable laws and regulations,

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(g) At least annually, evaluate the effectiveness of the Board as a body, the Audit Committee; Governance Committee; and Compensation and Management Development Committee,

(h) Determine the structure, composition, and responsibilities of the committees of the Board,

(i) Remain knowledgeable about Company affairs and developments through regular attendance at Board and Board committee meetings and review of meeting materials in advance of those meetings . . .

34. The Audit Committee Charter states, in relevant part:

The Audit Committee (the "Committee") of the Board of Directors (the "Board") of Merck & Co., Inc. (the "Company") is comprised solely of independent directors and is appointed annually by the Board.

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The Committee ***shall meet privately with the internal auditors and the independent public accountants*** at least quarterly and whenever else the Committee deems advisable. The Committee shall ensure that the independent public accountants are ultimately accountable to the Committee and the Board. ***The Committee's performance shall be evaluated annually by the Committee.***

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PURPOSE

Assist in the Board oversight of:

- The ***integrity of the Company's financial statements***.
- The Company's ***compliance with legal and regulatory requirements***.
- The independent public accountants' qualifications and independence.
- The ***performance of the Company's internal audit function*** and the independent public accountants.
- The ***accounting and financial reporting processes and system of internal controls over financial reporting of the Company and its audits***.
- The Enterprise Risk Management Process.

DUTIES AND RESPONSIBILITIES

The Company's management is responsible for preparing the Company's financial statements and the independent public accountants are responsible for auditing these financial statements. The Committee is ***responsible for overseeing the conduct of these activities by the Company's management and the independent public***

accountants, and the integrity of the Company's financial statements. The Committee is also responsible for providing the Report of the Audit Committee that SEC rules require to be included in the Company's annual proxy statement.

In carrying out its oversight responsibilities, the Committee shall perform the following functions:

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3. ***Oversee the Company's accounting, financial reporting process, internal controls and audits***. Consult with management, the internal auditors and the independent public accountants on matters related to the annual audit plan, audit procedures applied, audit and non-audit fees, status of federal tax returns and related reserves, the published financial statements, the accounting principles applied, any material changes thereto and the effects of regulatory developments or changes in accounting standards. Meet with the independent public accountants and internal auditors to discuss the results of their examinations. ***Annually review and discuss management's evaluation of the adequacy of disclosure controls and internal controls*** over financial reporting, including the attestation of such evaluation by the independent public accountants. ***Recommend to the Board of Directors that the audited financial statements be included in the Company's SEC filing*** (Annual Report on Form 10-K).

6. ***Review and discuss the annual audited financial statements and quarterly unaudited statements, including Management's Discussion and Analysis***, with management and the independent public accountants.

7. ***Discuss with management earnings press releases and financial information and earnings guidance*** provided to analysts and rating agencies. Review for compliance with regulations governing the use of non-Generally Accepted

Accounting Principles financial measures and related disclosure requirements.

8. Engage independent legal, accounting and other advisors, as the Committee determines necessary to carry out its duties, and obtain appropriate funding from the Company, as determined by the Committee, for compensating such advisors.

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11. Approve the scope of the internal audit plan for the current year and review the summary of results.

12. Review and concur on the appointment, replacement or dismissal of the head of internal audit. ***Review annually with the CFO, the performance of the head of internal audit***.

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18. Report regularly its activities to the Board in such manner and at such times as it deems appropriate. The Committee shall review with the Board any issues that arise with respect to the quality or integrity of Merck's financial statements, compliance with regulatory requirements, and the performance and independence of the independent auditors or the performance of the internal auditors.

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24. Review and evaluate the performance of the Committee and its members annually.

SUBSTANTIVE ALLEGATIONS

Background

35. Merck is among the world's largest pharmaceutical companies, touting itself as "at the forefront of research to deliver innovative health solutions that advance the prevention and treatment of diseases in people and animals." Specifically, the Company develops and manufactures prescription medicines, including biologic therapies, vaccines and animal health products.

36. In 2006, Merck began marketing Gardasil, a vaccine designed to protect against human papillomavirus, a common sexually transmitted infection. According to the Company, Gardasil can prevent certain types of HPV that can cause cervical, vaginal, vulvar, and anal cancer, as well as genital warts.

37. Throughout the Relevant Period, Merck management touted Gardasil, representing, among other things, that the drug would generate $11 billion in revenue by 2030. The Company boasted about its confidence in its ability to utilize successful consumer activation and education efforts regarding Gardasil's benefits to drive demand among eligible usage populations worldwide, primarily China.

38. Growing its China market was key to growing Gardasil sales, as evident in the Company's pre-Relevant Period filings. For example, in its Form 10-K filed on February 25, 2021 with the SEC for fiscal 2020, Merck noted that "the

Company's business in China has grown rapidly in the past few years, and the importance of China to the Company's overall pharmaceutical and vaccines business has increased accordingly."

39. Unfortunately, throughout the Relevant Period, Garadasil sales and revenue outlook were far below what Merck management had conditioned the market to expect through the following false and/or misleading statements.

FALSE AND MISLEADING STATEMENTS

40. On February 3, 2022, Merck held an earnings call in conjunction with the release of its fourth quarter and full-year fiscal 2021 ("2/3/22 Earnings Call"). During the 2/3/22 Earnings Call, Davis stated "we have many important franchises beyond oncology that we expect can drive durable growth into the next decade, including GARDASIL, which we believe can potentially double by 2030." According to Merck's Form 10-K filed with the SEC on February 25, 2022, Gardasil sales topped $5.6 billion in fiscal 2021, thus Davis's "double by 2030" statement forecasted Gardasil sales of over $11 billion within nine years.

41. On April 28, 2022, Merck released its first quarter results for fiscal 2022 and, in conjunction therewith, held an earnings call ("4/28/22 Earnings Call"). During the 4/28/22 Earnings Call, Davis boasted about Gardasil and its outlook, stating:

> ***Global demand for GARDASIL remains strong*** and growth will benefit from increased supply as a result of the significant investments we are making to expand manufacturing capacity
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> ***
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> Our vaccines portfolio again delivered ***excellent performance led by GARDASIL, which increased 60% to $1.5 billion***. Outside the U.S., significant growth was ***driven by strong underlying demand across key geographies, particularly China*** as well as increased supply. In the U.S., sales increased due to the timing of CDC purchases.
>
> ***Global demand for GARDASIL remains robust***, supported by strong clinical and real-world data as well as efforts to increase the recognition of GARDASIL as a vaccine that can help prevent certain HPV-related cancers in both females and males.

(Emphasis added).

42. Also during the 4/28/22 Earnings Call, the following exchange occurred between a UBS analyst and Litchfield:

> UBS Analyst: Congrats on the quarter. . . .I just wanted to piggyback on a GARDASIL question. Could you maybe just give us a little more detail on how you expect the GARDASIL supply to increase? And then maybe just help us think through what is the supply/demand mismatch right now? Some of your prior comments suggested that there may not be such. But I know you said supply has been an issue over the past sort of couple of years. So would love to get some expanded thoughts there.
>
> Litchfield: Thank you for the question. This is Caroline. So let me start first with the supply/demand. ***There is significant demand for GARDASIL. This cancer-preventing vaccine in the HPV area has only reached today 9% of the global eligible population. So there is significant runway ahead*** of us to protect lives and to drive growth for Merck. Indeed, ***we've stated that we expect the revenue in year 2030 to be double the $5.7 billion we achieved in 2021. So we have significant opportunity ahead of us.***

> In order to achieve that opportunity, we are building new facilities that will be coming online from 2023, 2024 and 2025. So ***we're going to have a step-up in the level of supply to the market*** that will happen over that period.
>
> Specific then to this year, we will see a continuation of the supply into the market as we did in 2021, albeit not quite at the same step-up that we achieved in 2021. So ***we remain really confident in our ability to drive strong growth for GARDASIL both in 2022 and the years to come***.

(Emphasis added).

43. On January 9, 2023, Merck management presented at the 41st Annual J.P. Morgan Healthcare Conference ("JP Morgan Conference") and, when discussing Gardasil, Davis stated:

> As you look at the durable growth drivers, what's important as you think about our vaccines business and our Animal Health business, these are very much annuity-like businesses with stable growth. And in both cases, we have a growing pipeline. So as you see, what we showed to be nice and robust growth across both, we expect that to continue into the long term. We've talked about starting with the vaccines business, ***which is really anchored in our product, GARDASIL, that, that product will continue to grow meaningfully***. And in fact, ***we expect it to more than double off of 2021 sales. So that -- if you look forward, what that means is growth in excess of $11 billion by 2030.***

(Emphasis added).

46. Also during the JP Morgan Conference, Davis stated the following during an exchange with a JP Morgan Chase analyst:

> JP Morgan Analyst: Great. Rob, on GARDASIL, this product clearly has exceeded expectations pretty consistently here. I know you talked about $11 billion-plus in 2030 sales. What do we need to do to bridge from where we are today to get to that peak sales level? And I guess

> part of my -- the second piece of that would be -- is that peak? Or is that just - - can this actually get even much larger than that given the...
>
> Davis: Well, if you look at where we are in the journey, obviously, it starts with a growing recognition, which I think is now really taking hold that as Dean [Li] said, this is a cancer vaccine, which is important. So we're going to continue to drive it. But if you look across the global population, it's still -- there's still a ***huge unmet need, and it's pretty underpenetrated***. . .
>
> And then increasingly, we're now, as we start to bring online additional capacity, we can start to drive also into the mid-adult population. We've obviously been limited to trying to do it more in the pediatric setting because we were limited in what we had. As we go to having an unconstrained situation, we'll be able to go more fully across all of these areas. And if you look at where we are today, actually in 2023, we're bringing online 2 new bulk facilities. Those will be ramping up between 2023 and 2025. ***So as we get to '25, we will be unconstrained in our ability to drive global demand***.
>
> In the meantime, we've shown we can drive productivity in our existing facilities. That's why we've been able to drive the growth we've had. And ***I'm confident you're going to see us grow. We're very confident in hitting the $11 billion number. I don't want to get into projections beyond that, but let's just say that the global need is still significant, and we're committed to trying to address it***.

(Emphasis added).

47. On April 27, 2023, Merck released its first quarter fiscal year 2023 results and, in conjunction therewith, held an earnings call ("4/27/23 Earnings Call"). During the 4/27/23 Earnings Call, Litchfield boasted about the Company's plan to accelerate Gardasil shipments to Zhifei, Merck's distribution partner in China, stating:

> Our vaccines portfolio delivered excellent growth led by GARDASIL, which grew 43% to $2 billion. Performance was driven by strong demand in major ex-U.S. markets particularly China as well as increased supply. ***Growth also benefited from an acceleration of shipments to China from the second half to the first half of the year to ensure the availability of product to meet heightened demand following the approval of the expanded indication of GARDASIL 9 for girls and women, 9 to 45 years of age***
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> ***
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> ***Finally, we are confident in our ability to drive strong growth of GARDASIL***, particularly in international markets. We are well positioned to protect many more people from HPV-related cancers now and over the long term. And given the strong global demand for the vaccine, we see an acceleration of growth for GARDASIL in the full year 2023 relative to 2022 but not quite at the same level of growth achieved this quarter.

(Emphasis added).

48. Also during the 4/27/23 Earnings Call, Davis stated the following during an exchange with a Wolfe Research analyst:

> Wolfe Research Analyst: I have a question on GARDASIL in China. So the GFA contract from your Chinese distributor published a couple of months ago shows really big purchase orders consistently for the next few years and it kind of trails off and declines. And it's interpreted literally it could suggest there was kind of a bolus effect going on where growth isn't linear. It goes up for a while, then it contracts as you work through warehouse patients. Is that how we should think about the longer-term uptake of GARDASIL in that particular market that it might not be linear?
>
> Davis: Yes. Just -- ***so if you look at the GFA contract, it's important to understand that the levels put in that contract are minimums***. And in fact, we have shown and our history has been that actually we have supplied well over the minimum. So I wouldn't interpret

> that as the literal forecast of the business in China because there's opportunities with the expanded age cohorts as we continue to drive penetration in what is still a large unmet population, there is opportunities to do better than what's in that contract. And if history isn't indicative of the future, we would expect to see that move forward. ***So I would not interpret that as implying a decline in GARDASIL in China over the coming years.***

(Emphasis added).

49. On October 26, 2023, Merck released its fiscal 2023 third quarter results and, in conjunction therewith, held an earnings call, during which Davis stated the following during an exchange with a JP Morgan analyst:

> JP Morgan Analyst: I just had a question on GARDASIL. We've seen obviously some very impressive growth over the past few years. But looking ahead, I'm just interested in how much more opportunity for -- you see for this franchise to ramp from here. So maybe just elaborate a little bit more on what are the kind of unmet needs at this point? Where is the biggest opportunity to continue to kind of roll out the product? And just ultimately, how much larger can this franchise become over time?
>
> Davis: Yes. Chris, no, I appreciate the question. So one, I would say we feel very proud of GARDASIL has -- strength of this business. And the fact that people increasingly recognize that we can fundamentally do what's the most important, which is prevent cancer, prevent cervical cancer, increasingly prevent certain head and neck cancers if we can get people fully vaccinated. So the fact that you are starting to see that progress is important.
>
> ***But as we look at the business going forward, I would start by saying we remain very confident that this is a business that's going to continue to grow and that we will achieve the expectation we've communicated of over $11 billion in revenue by 2030***. So nothing has changed in how we see the business. ***As you know, we've made significant investments in manufacturing capacity***. And from that perspective, now we're well positioned. We've brought on our 2 sites,

> and they're ramping now. And so we're doing quite well from that perspective.

(Emphasis added).

50. On February 1, 2024, Merck released its fiscal 2023 fourth quarter results and, in conjunction therewith, held an earnings call ("2/1/24 Earnings Call"). On the 2/1/24 Earnings Call, Litchfield touted Gardasil's growth during the quarter, stating that the Company's vaccines portfolio "delivered ***excellent growth*** led by GARDASIL, which increased 27% to $1.9 billion, driven by global demand, ***particularly in China***" (emphasis added).

51. Also during the 2/1/24 Earnings Call, Davis and Litchfield stated the following concerning Gardasil's growth and revenue opportunities in China, during an exchange with a Wolfe Research analyst:

> Wolfe Research Analyst: This is Adam on for Tim. On GARDASIL, a 2-dose regimen was recently approved in China. We're wondering if that poses a revenue problem. Potentially, it doesn't, if it just means that more supply gets spread out across more people, and Merck ends up selling just as many doses in total. Can Merck share its perspective here?
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> Davis: No, Adam, thanks for the question. ***So there's actually been Chinese competitors with an offering for some time actually in the Chinese market. And that market is large. We continue to believe in the eligible cohorts in just the urban females***, which is the Tier 1 to Tier 3 cities, is about 200 million -- a little over 200 million women. ***And so of that, we think probably about 30% have actually received vaccination. So you're still looking at 120 million, 130 million eligible population.***

> ***As we look at this and as we've seen over time, we continue to be very competitive. We're maintaining a vast majority of share in the private market. And really, you're seeing most of the local competitors go to the lower-tier cities and to a different population than we've been targeting. So that does not change our view of the growth potential in China long term***. Obviously, we will continue to face competition there, and we are positioning ourselves to continue to succeed there. But the approval you're talking about is not changing our view.
>
> Litchfield: The only thing I add, if I may, is we have significant opportunity to protect further females in China. ***At the end of 2023, we also submitted to the regulatory authorities our data on GARDASIL for males. So we're hopeful to introduce that in the Chinese market in the future.***

(Emphasis added).

52. On April 25, 2024, Merck filed with SEC on Form 8-K a press release announcing its first quarter fiscal year 2024 results. During the corresponding earnings call that followed ("4/25/24 Earnings Call"), Litchfield disclosed that the Company anticipated a reduction in Gardasil shipments to China during the coming quarter due to the acceleration in shipments during the prior year, stating:

> ***Our vaccines portfolio delivered strong growth, led by GARDASIL, which increased 17% to $2.2 billion, driven by global demand. Sales also benefited from the timing of shipments in China*** and CDC purchasing patterns in the U.S. VAXNEUVANCE sales grew to $219 million, driven by continued uptake of the pediatric indication in the U.S. and ongoing launches in international markets, particularly in Europe. In the U.S., VAXNEUVANCE sales also benefited from CDC purchasing patterns. Sales in our Animal Health business grew 4%. Livestock sales growth was driven by price actions as well as demand for swine

> and poultry products. Companion animal growth reflects price actions.
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> ***
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> As you consider your models, there are a few items to keep in mind. The increase in our sales guidance is driven by the strong performance across our current product portfolio, led by KEYTRUDA, which continues to experience growth from additional indications and patient demand. ***For GARDASIL, second quarter ex U.S. growth will be adversely impacted by shipment timing to China. This year, we expect more evenly distributed quarterly shipments to China***. Recall, in 2023, we accelerated shipments from the second half to the first half of the year, which primarily impacted the second quarter. ***Over the near and long term, we remain confident in our ability to protect many more people from HPV-related cancers and drive growth of GARDASIL.***

(Emphasis added).

53. Also on the 4/25/24 Earnings Call, Litchfield elaborated on the Company's China distribution "headwinds" in the following exchange with a JP Morgan analyst:

> JP Morgan Analyst: Just a couple of GARDASIL questions. You're pointing to a more evenly distributed China sales this year, and it seems like a tougher 2Q comp. But can you just directionally talk about growth for GARDASIL more broadly for the year? I guess the heart of it is still a healthy growth asset for you this year. And the second one on GARDASIL is if we were to move to a single dose of GARDASIL-9, what does that mean commercially and from a sales perspective for the franchise?

Litchfield: So in terms of the phasing of GARDASIL, as you pointed out, during 2023, we saw in China an acceleration of the shipment from the second half of the year to the first half of the year, specifically to the second quarter. What that's done is it's provided an actual tailwind to revenue growth ***in the first quarter for China, but it will provide a headwind more significant in the second quarter. And that's what we've called out.***

As we look at overall growth for GARDASIL, given where we are with the level of vaccinations across the world, given the manufacturing that we have been scaling up, ***we're confident in our ability to continue to drive growth during 2024. And in 2025, we will see our manufacturing capacity unconstrained so enabling us to further supply and support the market.***

As we've talked in the past, our opportunities for growth are significant as we look to continue to improve on adolescent vaccination rates, as we look to improve upon gender-neutral vaccinations, as we look to really activate the mid-adult segment, but increasingly get to the lower-income and middle-income markets, which will come at a different price point.

As we sit here today, continue to be confident in the outlook for GARDASIL over both the near and the long term. As we look at the possibility of a single dose of GARDASIL, the study that we are conducting will be a comprehensive study and will take some time to unfold. ***What we're seeing in the marketplace currently is where certain low-income markets are implementing a single-dose regimen, they are also increasing the numbers of people they are vaccinating by broadening the age cohort or also opting to vaccinate males at this stage. We'll have to be long term how the data plays out with regards to a single dose to ensure that we will price our vaccine based on the benefit that we're bringing and we vaccinate as many people in the world that we can.***

(Emphasis added).

The Truth Emerges

54. On July 30, 2024, Merck's management held an earnings call to discuss the Company's second quarter fiscal year 2024 results ("7/30/24 Earnings Call"), during which Litchfield announced purportedly sudden setbacks with regard to Gardasil's China sales from Zhifei to purchasers down the distribution chain, stating:

> Our vaccines portfolio delivered solid growth. GARDASIL sales increased 4% to $2.5 billion. In the U.S., sales benefited from price as well as demand and favorable CDC purchasing patterns. Outside the U.S., higher demand across many international markets was partially offset by the timing of shipments to China
>
> ***
>
> For GARDASIL, over the past few years, we've benefited from extremely strong demand in China, including from the expanded indication for GARDASIL 9 to the 9- to 45-year age cohort in late 2022. ***In the second quarter, however, there was a significant step-down in shipments from our distributor and commercialization partner, Zhifei, into the points of vaccination compared with prior quarters, resulting in above normal inventory levels at Zhifei***. We are working closely with them to more fully understand the dynamics that caused this change. As we learn more, we will assess future shipments to our partner and work to bring their inventory back to more normal levels. ***If shipments from Zhifei into the points of vaccination do not increase, it is likely that we will ship less than our full year 2024 contracted doses by the end of this year.***
>
> We believe the opportunity in China remains very attractive as there are more than 120 million females in the addressable population living in Tier 1 to Tier 5 cities who have not yet received the protection of an HPV vaccine. As we said before, it will take increasing efforts to educate and activate the next wave of patients. ***Together with Zhifei,***

> ***we are focused on and committed to investing in additional resources and patient education on the value of GARDASIL given the important benefit it provides. We also look forward to the potential approval for males, which we believe represents a meaningful opportunity.***
>
> More broadly, ***we remain confident in the opportunity for GARDASIL globally based on the protection it provides against HPV-related cancers and low immunization levels overall, and continue to believe we will achieve sales of over $11 billion by 2030***. Our initial launch of WINREVAIR is having a positive impact for patients. We are very pleased with its performance and look forward to supporting more patients in the U.S. and across the globe.

(Emphasis added).

55. Also on the 7/30/24 Earnings Call, Davis and Litchfield had the following discussions with analysts:

> JP Morgan Analyst: Congrats on the progress. I just want to kick off with just a question on GARDASIL dynamics in China. Maybe just a two-part question here. First, can you quantify what percent of your international sales are coming from China? And just any additional color on what drove the step-down in 2Q? I'm just trying to get my hands around this.
>
> And maybe as part of that, the 2024 guidance update, is the potential for shipments to come below the 2024 contracted doses now reflected in that guidance? Or would that represent an incremental headwind to numbers to the extent that played out?
>
> Davis: Great. Thanks, Chris, and thanks for the question. And I'll maybe take the first part and then ask Caroline to comment on guidance. To your question, China represents about – for GARDASIL of about 60% to 70% of the numbers. So that kind of gives you a sense of it. But maybe to give some context on what we saw in the quarter, and as we look to the full year and where we see things going. So let me start maybe by talking a little bit about the dynamics.

The opportunity that exists for GARDASIL in China remains very attractive with more than 120 million eligible females in China yet to be protected against HPV, which represents about 60% to 70% of the eligible population. And I think we all recognize the benefits of protection against HPV-related disease is clear and importantly, aligns with China's Healthy 2030 initiative. So the underlying support, we continue to believe is there.

In addition, we have filed for the male indication, which has been accepted and represents another significant opportunity. So as we think about China, I just want to set the context because I think it's important to understand, we continue to have a very meaningful opportunity in the China market. What's unclear to us and what we're trying to understand is that during the second quarter, we saw a significant step-down in shipments from Zhifei to the points of vaccination.

The reductions during the second quarter was surprising, and I would point out was a meaningful departure from prior trends we've seen both throughout really all of 2023 and into the first quarter of 2024.

So as we look at this, we're wanting to understand what would cause the trend break we saw. And I can tell you what we know as of now is we believe there could be multiple factors that may be contributing to this dynamic, and ***we're working closely with our partner to try to tease out what exactly is happening.*** But overall, the data we track indicates that the whole HPV market in China experienced this step-down. So this is not a Merck-specific event.

And importantly, we see the market share for GARDASIL as stable or actually increasing right now in the marketplace. ***We don't believe this step-down, therefore, represents any change in the competitive dynamic, and GARDASIL remains by far the market leader.*** We do believe, however, that based on the intelligence we've gathered, activity in the HPV vaccine area has been recently impacted by China's antibribery and anti-corruption drive which, as you know, started really last year.

And up to that point, we really haven't seen much impact, but we do believe we are starting to see it now. And this is really driven by the fact that in the health care industry, there has been, as a result of this, a reduction in scientific engagement, primarily in the CDC within China and fewer immunizations. So we need to tease that out more. ***And in addition, we did see reduced levels of promotional support for HPV vaccination at the same time that our distribution partner, Zhifei, broadened its portfolio.*** So we'll need to get more into that.

But obviously, we have a very strong relationship with Zhifei, and ***we already have started to put in place a robust plan to invest in increased promotional efforts really designed to drive awareness, education and activation of the remaining female opportunity. And this includes both resources at Zhifei and more selling resources and promotional resources as well as promotional resources being deployed directly from Merck. So as we look forward, we'll have to see how all of these activities impact shipments to the point of vaccination.*** And as we learn more, we'll assess future shipments to China with our partner. So hopefully, that gives you a sense of what we're seeing.

But I just would reiterate one other point. And that's, that as we look to the long term, given both the opportunity in China, I mentioned for the 120 million remaining females as well as the potential for the male indication, outside of China, we saw double-digit growth across all regions in the quarter. So we continue to be on track, doing well and driving growth in this important vaccine. And that's why you heard Caroline in our prepared comments reiterate our confidence in the $11 billion number by 2030, even taking into account what we saw China happening in China this quarter.

So with that, maybe I'll turn it over to Caroline and she can address your guidance-specific question. Caroline?

Litchfield: ***Thank you, Rob. So Chris, in terms of our guidance, we've assumed a range of scenarios, from providing the fully contracted 2024 doses during this year to providing something less than that. If I anchor to the midpoint of our guidance, we have been measured in assuming a scenario that has less than the contracted 2024***

GARDASIL doses shipped to China. And even with that, we were able to raise our guidance at the midpoint by $200 million.

And that's really as a result of the underlying momentum that we have in the rest of our business, including oncology, with KEYTRUDA and WELIREG. It includes Animal Health with the launch of BRAVECTO in injectable as well as the acquisition of the Elanco aqua business. And we remain confident in our outlook for WINREVAIR and the opportunities to drive patient impact and growth consistent with our high expectations.

***

Evercore ISI Analyst: Can I just dial down the GARDASIL point just a little more? Rob, I know you mentioned there's an anti-bribery, anti-corruption drive going on in China, which started last year. But it also feels like some of the shipment delays are happening, perhaps a few months ahead of potential competition hitting the market as well. So could you speak to whether there's any future contracting happening and whether your long-term price integrity will stay intact on GARDASIL in China?

Davis: Yes. No, thanks for the question. ***So everything we're seeing in the marketplace, I would just reiterate, would point to dynamics that we don't see the competition, the future potential competition***. I think you're referring to the fact that we very well could see a 9-valent sometime next year come into the marketplace. So I don't believe from anything we've heard in the marketplace, from competitive intelligence as well as what we're hearing from Zhifei that, that is what's happening here.

As we look forward, and Caroline can comment specifically, ***we have always expected that as we see the peak move through from the indication we got for the expansion of the age cohort, that you would see a flattening out over time of the demand in China. And then that, for women, specifically, and then we would bring on the male indications that should allow us then to continue to drive the business forward from there. Nothing has changed in that dynamic in what***

we're seeing right now. So as we look forward, our belief in China being a significant contributor is unchanged.

But I'll let -- maybe Caroline can speak specifically as we're thinking about some of the guidance around how we think about next year.

Litchfield: ***So what I would add is we have always contemplated that we would have a 9-valent competitor within the Chinese market. As such, the current contracted doses with Zhifei for 2025 are less than what the contract is for 2024***, as we would expect to participate in that market but understand a competitor would likely gain share in that market. ***We also, though, as we said in the prepared remarks, has the potential opportunity of a male launch in China***.

And we are hopeful for an approval with GARDASIL 4 and 9 by first half of next year, and be coming to the market at that stage. ***So we are confident that China will remain an important part of our GARDASIL business as we move forward and, more importantly, are confident in the opportunity to drive GARDASIL longer term, the $11 billion that we've stated.***

***

Wolfe Research Analyst: I know you're reiterating your $11 billion figure, at least $11 billion in 2030. The shape of the curve over that time in China specifically, which is only a part of that number, are there likely to be periods where year-on year sales actually contract beyond 2024 and the inventory issue?

Because it does seem like pricing is really going to be a risk here, the way pricing works with vaccines in China. And some of these other offsetting indications like males are going to take time to launch. So it seems like there may be periods there where you could have year-on year declines in sales over the next, let's say, 5 or 6 years. So if you could just describe the shape of that curve, please?

Davis: Yes. Sure. ***So as we look at it, we do expect you will see a flattening of the curve, as we see the female indication be more fully penetrated. Obviously, more to go there, given what we believe is still***

the addressable population. And then it will ramp back to growth as the male population comes on in full. So that is what we're expecting to happen.

And on the pricing point, I think it's just important to understand the way this market works and how we operate in the market. We sell into Zhifei. Zhifei then is responsible for doing the bidding with the provinces, and actually then determining ultimately that end sale to the point of vaccination. ***As we look forward, I think it's important to understand that GARDASIL as we think about the addressable population, we continue to believe, will be a highly sought-after vaccine even in the face of competition.*** And we're dealing in an overall population when we quote the 200 million total females, of which we would say we're 30% to 40% penetrated today. That's really in the Tier 1 to 5 cities that we think can afford a cash pay market. ***The total population accessible in China is much bigger.***

And so I don't think we should assume we're all competing for that small slice. There's a much bigger slice we've chosen not to go for that bigger piece because obviously, we can't get into the local vaccination program because we don't produce GARDASIL in China.

Our competitors will be able to do that. So I think I would just caution all to not view it as a zero-sum game.

I think there's still a market expansion opportunity in China that will benefit both us and the competitors. ***And frankly, the other thing we have to see is how quickly will the male indication be given to others beyond us. We believe there's a chance we could be [sitting alone with that] as well. So the dynamics need to play themselves out.*** But I think we need to first understand is what we're seeing in the quarter specific, a short-term event or something else.

And that's still not clear because I would just point that the trend break was pretty significant. ***It's not what we've seen in any of the markets that you would expect. And that's why we're a little hesitant to say this is just demand in China.*** And also, I would also bring back the fact that actually, if you separated out what happened in China, we had one of

our strongest quarters in every other market around the world and with strong double-digit growth. So that's -- those are all dynamics that will have to play themselves out.

***

Wells Fargo Analyst: And just trying to understand the long-term growth path for GARDASIL, it seems like, and correct me if I'm wrong, [a lot felt] it would depend on raising awareness in those Tier 1 to 5 cities and male vaccinations. So the question is, of those Tier 1 to 5 cities, where do you think there is bigger opportunity? Because, I mean, going to Tier 4 and 5 could be challenging. And then based on your male vaccination experience in the developed world, how should we think about China in that context?

Davis: Yes. So if you look across the Tier 1 to 5 cities, we're actually -- when we quote that we're 30% to 40% penetrated, and again, this is just to the females. ***So this is -- we're only speaking to females right now. We're 30% to 40% penetrated. We're a little bit less penetrated. I think we're on kind of say, 30th percent in the 4- and 5-tier cities, and we're around 40% in the 1 to 3. So there's not a huge spread between the Tier 1 to 3 and the 4 to 5. So we will continue to focus efforts across all of those areas as we have been to date.***

And then it's a whole different exercise to activate the male population across that same area which is, frankly, doesn't -- isn't there today because of the fact that we don't yet have the indication.

***

The context of how we will drive growth has multiple levers for us to look at to do that. ***And that's why we are confident in the $11 billion number long term. And I think that's important as we shape the overall context of the discussion.***

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Jeffries Analyst: And really helpful color on GARDASIL. Just one more here. Looking at the latest Zhifei contract, it looks like there's

> around $4.5 billion in potential sales for 2024. That's projected to decline in 2025 and 2026 to around $2.5 billion. Historically, however, it looks like you've always exceeded that contracted figure. So just to be clear, does the contracted decline in sales over the next 2 years bake in the upside for potential male approval? And should we expect the Zhifei contract to get renegotiated as we get further clarity on demand?
>
> Litchfield: Thank you for the question. ***So the Zhifei contract that we have at this stage is focused on the current approval that we have in the market***. So it's really focused on the female population in the age cohort 9 through 45. ***As we move forward and we have a male indication, we will, of course, be working with our partner to have the appropriate doses so that we can protect as many males as possible***.

(Emphasis added).

56. Finally, Davis closed the 7/30/24 Earnings Call with the following statement:

> But I maybe would close by just bringing back the confidence we see in the business, both in the short term and the long term. ***Obviously, we'll work through what we see happening with GARDASIL in China. But the fact that we see strengthening, and I would call them green shoots around GARDASIL everywhere else in the world, gives us confidence in the $11 billion for that, as we've talked about*** . . .

57. On this news, the price of Merck's common stock declined nearly 10%, from $127.78 per share on July 29, 2024 to $115.25 per share on July 30, 2024.

58. Still, Merck management continued to mislead the market with regard to Gardasil's status and prospects. Specifically, the Company continued to misrepresent management's understanding of the issues surrounding the slowdown in Gardasil vaccinations in China and Zhifei's inflated inventory levels. In doing so,

the Defendants deceptively claimed confidence in Gardasil's continued growth in China within the existing Gardasil eligible population of women and planned approval for males. Management further concealed their plan to reduce Gardasil's distribution to China.

59. On October 31, 2024, Merck announced its results for the third quarter of fiscal year 2024. During the corresponding earnings call on the same day ("10/31/24 Earnings Call"), Davis minimized the ongoing issues in China and reaffirmed the Company's $11 billion in sales by 2030 mantra for Gardasil:

> As anticipated, results also reflect a decline in GARDASIL sales year over-year. Notably, however, we achieved strong double-digit growth for GARDASIL in almost every major region outside of China.
>
> ***In China, consistent with the expectations we discussed on our prior earnings call, we shipped less to our commercialization partner, Zhifei, and we expect fourth quarter shipments will be at a similar level to the third quarter***. Overall channel inventories of GARDASIL have decreased, which is directionally encouraging, while inventory at Zhifei remains above historical levels. ***We are highly focused on this market and are making progress with Zhifei to increase promotional resources and patient education efforts***. We expect these efforts to translate to increased patient activation and demand, but as we've said, this will take time.
>
> Taking a step back, we're proud of the role that GARDASIL is playing in helping prevent certain HPV-related cancers. There's a wide range of long-term growth opportunities around the world due to the tremendous remaining need to protect more individuals, with less than 10% of the global eligible population vaccinated and meaningful opportunities to improve vaccination completion rates, gender-neutral vaccination rates, mid-adult coverage and access in low- and middle-income markets. ***This includes in China, where there is an attractive long-term***

> ***opportunity, given the significant number of females yet to be immunized and the potential approval for males next year. We're highly focused on using our scale and strong capabilities to drive education and awareness of the benefits of HPV vaccination and to reach and protect more patients globally. As such, we remain confident in our goal of achieving greater than $11 billion of [sic] sales by 2030.***

(Emphasis added).

60. Also on the 10/31/24 Earnings Call, Davis made the following statements in response to questions from several analysts:

> UBS Analyst: Just on GARDASIL, given the inventory levels remain elevated, you've noted this declining demand. How should we think about dynamics as we head into 2025, given that increase in promotional activity, but that's balanced by the inventory work down? Will you take time? Or do you have any color on when we'll see an inflection to that returning growth?
>
> Davis: ***Great. Thanks for the question. Obviously, we're very focused on GARDASIL in China.*** But maybe just to step back for a second, we continue to be very proud of the contribution that GARDASIL is making for patients and people around the world to really address and hopefully eliminate long-term cervical cancer as well as other HPV-related cancers. So that important work will continue.
>
> And importantly, as we commented in our prepared remarks, while China did decline, and I'll speak to China in a second, overall, we saw strong double-digit growth in really nearly every other region around the world, which is showing the progress we're making and which is why we continue to have such confidence in the long-term potential for this.
>
> ***But as it relates to China specifically, and as we think about 2025, I don't want to give specific guidance because obviously, we're still working through our 2025 plan. But what I would say is we do expect to continue to see a decline in shipments into China into 2025. And***

as we had highlighted before, this is happening a little bit earlier than we originally expected. But we had always expected that over time, as we work through the bolus, we would see the female opportunity decline and then hopefully seeing growth come with bringing the male opportunity, which we would expect to see with approval, assuming it comes next year. So that's how we see it progressing.
So as we think about 2025, we see China really in the $2 billion to $3 billion range as far as an opportunity for 2025 and for the next several years with the opportunity in males really being the growth driver.
And at that level, we would expect for overall Merck that you're going to continue to see, based on the portfolio we have, solid growth. So I think that's just important to kind of frame where we're seeing things but understanding we're focused on this, we're bringing our efforts to drive demand and we're going to make progress. We are making progress, but it's going to take some time.

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JPMorgan Analyst: Just another one on GARDASIL. Rob, I believe you said kind of $2 billion to $3 billion per year opportunity for China over the next few years. Just a couple of quick ones there. First, what does that compare to where China is going to shake out for Merck this year? And is that $2 billion to $3 billion number what was reflected in the $11 billion longer-term target?

Davis: Yes. So to give you just a sense of where we are, and we don't normally give product-level guidance or specifics on a quarterly basis. But given the importance and focus on GARDASIL, ***just to give you a sense of where we were with China GARDASIL in the third quarter, it's about approximately $500 million in the third quarter. And as we said, we would expect to ship about the same amount in the fourth quarter. So you should expect that the fourth quarter itself would also be in that $500 million range. And so that kind of gives you a sense of where we are***.

So as you look forward to 2025, obviously, as we think in 2025 and over the next several years, if you're running in that $2 billion to $3 billion range, that's why we made the comment that with that and given the other opportunities we see around the world, we remain

confident in our ability to get to the $11 billion by 2030. So we are contemplating that $2 billion to $3 billion over the next several years in China as the contribution that it would make to get us to where we need. ***Understanding also that long term, we do expect to be able to have the potential for growth driven by the male opportunity in China*** and then, obviously, continuing to drive more broadly around the rest of the world.

***

Morgan Stanley Analyst: Great. Maybe just one question and one clarification. Just on the GARDASIL side, Rob, that's the $2 billion to $3 billion includes the males or it does not include the males? Sorry, I was a little unclear based on the last response . . .

Davis: Yes. So I'll take the first part of that question, Terence. ***So the answer is yes. the $2 billion to $3 billion over the next several years does include male, but we have the opportunity as you look longer term to drive growth with that opportunity. That was really the point we were trying to make.***

***

Evercore ISI Analyst: I have -- I wanted to focus on GARDASIL just a little more. That was very helpful commentary, Rob. You mentioned $500 million in sales in 3Q and 4Q to China, which obviously is $2 billion run rate. My question is, was that shipping to demand? Because if so, what that means is inventory sitting at your [indiscernible] is still something that would need to be worked down in 2025 as well as possible 9-valent generic entry -- sorry, 9-valent local competition entry in 2025 as well. How do you factor those 2 dynamics into thinking about the 2025 number of $2 billion to $3 billion in China?

Davis: Yes. So if you look at what's happening in the overall marketplace and just to give you a sense, from an inventory perspective, maybe starting there. ***If you look at overall inventory levels in China, they did come down. And that's taking into account, and this is for GARDASIL.*** GARDASIL at Zhifei, which frankly remains high and grew slightly, but that was more than offset by reductions in the CDCs

and the points of vaccination. So that's a good sign that we're seeing overall inventories coming down, which also would point to the fact that as we're looking at demand, which we're seeing stabilize, we think we're at a position now whereas we're starting to talk about what we're shipping. ***Our expectation is we are shipping below demand***.

So we have been working very constructively with Zhifei to think about this, both as what we're doing in this year is, frankly, as well as we're continuing to have constructive dialogue around 2025. ***Our intention would be to balance the need to get product into the marketplace to meet the demand at the same time, allowing for Zhifei to bring down their inventories over time. So we're very thoughtful on how we're thinking about it, and we've done that, taking into account our expectations of both the female competitive launch that could come next year, but also the opportunity that a male approval early next year could allow us to have. So all of those factors are in as we think about that $2 billion to $3 billion number.***

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TD Cowen Analyst: I mean all things considered, is it still possible to see global GARDASIL growth in 2025? And Rob, you noted at the start that recovery in China will take time, but it sounds like you have good visibility now because you're giving this $2 billion to $3 billion guidance for GARDASIL in China. So I'm unclear what it is that we're waiting for.

Davis: Well, what we're talking about taking time is basically to work down the inventory and to then build demand over time so that we can continue to drive that market. ***What we're giving you is kind of what we see as the baseline of China. Our hope is that we'll do better.*** And we're going to put the work in to do better and to continue to drive long term. I think that what I'm trying to make sure everyone hears is this isn't going to be solved next quarter. It's going to take us through probably 2025, but we're thoughtful on how we're doing it. We're working with Zhifei in a constructive manner to do it. So those are the elements are going to take time because we need to build the demand. ***We know the opportunity is there with 120 million females still out there to go after and with potentially 200 million males with the male***

> ***opportunity. We have to activate that demand to make sure we can drive that business***. So that's really what we're focusing on.
>
> As far as it relates to GARDASIL for 2025, I don't think we really want to get into giving product line guidance right now. We were very specific to China because of the concerns that were there. And I wanted to make sure you know that we see solid overall growth for Merck because that's important to have context. But beyond that, we normally wouldn't be giving guidance at this point in time.

(Emphasis added).

61. On February 4, 2025, Merck filed with the SEC on Form 8-K a current report announcing its fourth quarter and full year 2024 financial results ("2/4/25 8-K"), which disclosed that Gardasil sales "declined 3% to $8.6 Billion" and that the decline was "primarily due to lower demand in China. . ."

62. Also on February 4, 2025, the Company held an earnings call to discuss the 2/4/25 8-K ("2/4/25 Earnings Call"), during which Merck management further discussed the Gardasil difficulties in China and their effect on the Company's projections:

> Now turning to our results and outlook. We delivered strong growth in 2024, reflecting demand for our innovative portfolio . . . We also saw higher demand and achieved strong sales for GARDASIL outside of China.
>
> ***
>
> As we close out 2024 and entered 2025, the market dynamics for GARDASIL in China have remained challenging. Like many other companies, we've seen increased pressure on discretionary consumer spending, including across the vaccine space more broadly, and

demand for GARDASIL has not recovered to the level we had expected. As a result, ***overall channel inventory remains elevated at above-normal levels.***

In light of this and based on further discussions with our commercialization partner, Zhifei, over the past couple of weeks, in particular regarding their most recent financial disclosure and working capital levels, ***we've made the decision to take a new approach and temporarily paused shipments to China beginning this month and through at least midyear. We believe taking this action now more rapid reduction of inventory and help support the financial position of our important and valued partner.***

Importantly, we believe China still represents a significant long-term opportunity for GARDASIL given the large number of females and now males with our recent approval that are not yet immunized. And we remain both committed and well positioned to maximize this potential for the long term. Outside of China, demand for GARDASIL remains robust, and we expect strong growth this year and well into the future.

***

Now turning to our 2025 non-GAAP guidance. We expect revenue to be between $64.1 million and $65.6 billion, representing growth [up to 4%], excluding a negative impact from foreign exchange of approximately 2% using mid-January rates. ***For GARDASIL in China, our guidance assumes no further shipments at the low end and less than $1 billion at the high end***. Excluding sales of GARDASIL in China in both 2024 and 2025 and the negative impact from foreign exchange, total company growth is expected to be 7% to 9%.

***

Looking at GARDASIL longer term. While we believe there continues to be a path to the $11 billion, we feel it is prudent to withdraw this target given uncertain timing of an economic recovery in China. Our growth expectations outside of China for this important vaccine remain

> unchanged and and we are well positioned to protect more lives and drive strong growth beyond 2025. . .

(Emphasis added).

63. Merck's February 4, 2025 statements contradicted those issued previously, including those made during the 7/30/24 Earnings Call and the 10/31/24 Earnings Call, during which Merck management purported to understand the issues surrounding Gardasil's slowdown in China and Zhifei's inflated inventory, and that the Company was successfully reducing Gardasil shipments to allow Zhifei to reduce the inventory backlog.

64. Merck's common stock price declined dramatically on this news, from $99.79 per share on February 3, 2025 to $90.74 per share on February 4, 2025, a nearly 10% decline.

65. The damages Merck has suffered are a direct and proximate result of the Individual Defendants' breaches of fiduciary duties. Thus, as a result of the misconduct alleged herein, Individual Defendants are liable to the Company.

DERIVATIVE AND DEMAND FUTILITY ALLEGATIONS

66. Plaintiff brings this action derivatively in the right and for the benefit of Merck to redress Individual Defendants' breaches of fiduciary duty and other violations of law.

67. Plaintiff will adequately and fairly represent the interests of Merck and

its shareholders in enforcing and prosecuting its rights.

68. The Board currently consists of the following thirteen directors: Defendants Davis, Baker, Coe, Craig, Glocer, Mayo, Mourey, Rothman, Russo, Seidman, Thulin, Warden and non-party Surenderalal Karsanbhai.

69. Plaintiff has not made any demand on the present Board to institute this action because such a demand would be a futile, wasteful and useless act, for the following reasons:

a. The Individual Defendants face a substantial likelihood of liability for, among other things, approving or otherwise not preventing Merck's issuance of its financial statements that, among other things, materially overstated the true state and outlook of Gardasil, including greatly exaggerating demand in China for the drug resulting in significant financial and reputation losses to Merck;

b. The Individual Defendants further face a substantial likelihood of liability for, among other things, approving or otherwise not preventing Merck's issuance and omission of statements accurately portraying the Company's inventory; customer demand; and likely sales channel manipulation;

c. During various times of the Relevant Period, pursuant to the Company's Audit Committee Charter, the six Audit Defendants, Baker, Craig (Chair), Mayo, Rothman, Seidman and Warden, were responsible for, among other things, reviewing the Company's annual and quarterly financial reports and

reviewing the integrity of the Company's internal controls. The Audit Defendants breached their fiduciary duties of due care, loyalty, and good faith, because the Audit Committee, *inter alia*, allowed or permitted the Company to disseminate false and misleading statements in the Company's SEC filings and other disclosures and failed to recognize or correct Merck's internal control failures. Therefore, the Audit Defendants each face a substantial likelihood of liability for their breach of fiduciary duties and any demand upon them is futile;

d. Moreover, the Audit Defendants failed to maintain the level of oversight required, including that the requirements that the Audit Committee discuss with management and review with the Board, the legal and regulatory requirements applicable to the Company and its subsidiaries and the Company's compliance with such requirements and as appropriate, make recommendations to the Board with respect to the Company's policies and procedures regarding compliance with applicable laws and regulations;

e. Therefore, the Audit Defendants each face a substantial likelihood of liability for his or her breach of fiduciary duties and any demand upon the Audit Defendants is futile;

f. The principal professional occupation of Davis is his employment with Merck, pursuant to which he has received, and continues to receive, substantial monetary compensation and other benefits;

g. Moreover, Davis personally made most of the false and/or misleading statements on behalf of management, as alleged herein; and

h. Davis faces a substantial likelihood of liability for his breach of fiduciary duties, including myriad misstatements, and

i. Therefore, any demand upon Davis is futile.

COUNT I

Against Individual Defendants for Breach of Fiduciary Duties

57. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

58. As alleged herein, each of the Individual Defendants violated and breached his or her fiduciary duties of loyalty and good faith by causing or allowing the Company to disseminate to Merck shareholders materially misleading and inaccurate information through, *inter alia*, SEC filings, press releases, conference calls and other public statements and disclosures as detailed herein. These actions could not have been a good faith exercise of prudent business judgment to protect and promote the Company's corporate interests.

59. Also as alleged in detail herein, each of the Individual Defendants had a fiduciary duty to, among other things, exercise good faith to ensure that the

Company's public statements were accurate and exercise good faith in taking appropriate action to correct the misconduct and prevent its recurrence.

60. Individual Defendants, most notably those serving on the Board's Audit Committee, willfully ignored the known and pervasive problems with Merck's internal controls and practices and procedures and failed to make a good faith effort to correct these problems or prevent their recurrence.

61. As a direct and proximate result of the Individual Defendants' foregoing breaches of fiduciary duties, the Company has suffered significant damages. Thus, as a result of the misconduct alleged herein, the Individual Defendants are liable to the Company.

COUNT II

Against Individual Defendants for Unjust Enrichment

62. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

63. By their wrongful acts and omissions, Individual Defendants were unjustly enriched at the expense of and to the detriment of Merck.

64. Plaintiff, as a shareholder and representative of Merck, seeks restitution from Individual Defendants, and each of them, and seeks an order of this Court disgorging all profits, benefits, and other compensation obtained by Individual

Defendants, and each of them, as a result of their wrongful conduct and fiduciary breaches.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment as follows:

A. Declaring that Plaintiff may maintain this derivative action on behalf of Merck and that Plaintiff is a proper and adequate representative of the Company;

B. Against Individual Defendants and in favor of the Company for the amount of damages sustained by the Company as a result of Individual Defendants' breaches of fiduciary duties;

C. Directing Merck to take all necessary actions to reform and improve its corporate governance and internal procedures to comply with applicable law and to protect the Company and its shareholders from a repeat of the damaging events described herein, including, but not limited to, putting forward for shareholder vote resolutions for amendments to the Company's By-Laws or Articles of Incorporation and taking such other action as may be necessary to place before shareholders for a vote a proposal to strengthen the Board's supervision of operations and develop and implement procedures for greater shareholder input into the policies and guidelines of the Board;

D. Awarding to Merck restitution from Individual Defendants, and each of them, and ordering disgorgement of all profits, benefits and other compensation obtained by Individual Defendants;

E. Awarding to Plaintiff the costs and disbursements of the action, including reasonable attorneys' fees, accountants' and experts' fees, costs and expenses; and

F. Granting such other and further relief as the Court deems just and proper.

JURY DEMAND

Plaintiff demands a trial by jury.

Dated April 9, 2025

Respectfully submitted,

THE WEISER LAW FIRM, P.C.

s/ James M. Ficaro
JAMES M. FICARO (2010-00123)
jficaro@weiserlawfirm.com
Four Tower Bridge
200 Barr Harbor Drive, Suite 400
West Conshohocken, PA 19428
Telephone: (610) 225-2677

MERCK & CO., INC. VERIFICATION

I, Vladimir Gusinsky, on behalf of The Vladimir Gusinsky Revocable Trust, hereby verify that I am familiar with the allegations in the Verified Shareholder Derivative Complaint, and that I have authorized the filing of the Verified Shareholder Derivative Complaint, and that the foregoing is true and correct to the best of my knowledge, information, and belief.

Date: 4/3/2025

V. Gusinsky

Vladimir Gusinsky